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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/039,789 | 03/16/98 | CARVER | E 4537-01-2 |

IM52/0809

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| EXAMINER | |
|---|---|
| SODERQUIST, A | |
| ART UNIT | PAPER NUMBER |
| 1743 | 28 |

DATE MAILED: 08/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/039,789 | Carver et al. |
| **Examiner** | **Art Unit** |
| Arlen Soderquist | 1743 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Jun 14, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *27-30, 32-35, and 38-45* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *27-30, 32-35, and 38-45* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 27
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. It is noted that the inventorship was changed in the parent application. Since the application was filed with a copy of the original declaration and there was no request to delete inventors, examiner is assuming that the instant inventorship includes two inventors.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 27-30, 32-35 and 38-45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto in view of Kabata, Taylor, Dixon, Halliday, Robertson or O'Daly (last reference newly cited and applied) and Callan or Weiser (JAVMA 1987). In the figures and associated discussion Yamamoto teaches an automated blood analyzer and method for making blood particle analyses. Yamamoto teaches at least one pump (102,111,162) in fluid communication with a mixing chamber (113-115) and a source diluent. A sample (101) is removed from a sample container by a sample probe (117,161) and the at least one pump transfers the sample and diluent to the mixing chambers. Since the fluid flow arrows of figures 2 and 5 show pumps 102, 111, and 162 as capable of both suction and positive pressure, they are positive displacement pumps. Two different lysing reagents (141,142) are also transferred to the mixing chambers by a vacuum pump. The blood sample is analyzed for particles through a sensing orifice (158). The device has a controller (figure 3) for controlling the device and analyzing the result. Also Figure 4 shows that the result is obtainable in around 47 seconds. Yamamoto does not teach

a multiple species database having different lysing compositions for each species which are mixed for blood samples from the different species.

In the paper Kabata teaches the analysis of the hematologic values of peripheral blood from normal adult rabbits using five different automated flow cytometers. During the analysis the software designed for human blood analysis was used. In the second paragraph of page 613 Kabata teaches that it is known that rabbit blood cells are known to differ from human blood cells in several aspects and suggests adapting the software for animal blood. Pages 614 - 615 discuss how the different automated systems work to obtain the various blood cell populations. It is noted that most of the automated systems incorporate a lysing reagent in the various methods. The rest of the article reports the results and discusses its significance. Of importance to the instant claims is the discussion on page 618 regarding the problems in determining the white blood cell differential counts. The first paragraph also teaches that the leukocytes of rabbits have several morphologic features that differ from human leukocytes. In the second to last paragraph Kabata teaches that automatic counting of **all** white blood cell sub-populations in animals would require different software. Also taught was the failure of Technicon software designed for use with rat or dog blood to give as reliable of results for rabbit blood as the software designed for humans. Since the Technicon software for rats and dogs give different results, the two sets of software are different.

In the paper Taylor compares several treatment procedures for preparing different cell populations for flow cytometric analysis. They teach that although each works, one of the methods works better than the others in flow cytometric analysis.

In the paper Dixon discusses electronic counting of dog leucocytes. In particular, the discrepancies arising from calibration with Coulter standard 4C and with the hemocytometer. The size distributions of leucocytes in canine blood and in standard 4C are markedly different. The use of 4C to calibrate Coulter counters may result in the selection of a threshold setting for canine leucocytes which is too high. Repeated hand counting may be used as a method of calibration, but regular discrepancies occur between hand and electronic counts which are attributable to the differing lytic actions of the diluents used, acetic acid having a more marked effect than

commercial Zapoglobin. The degree of discrepancy between hand and electronic counts varied in individual dogs suggesting that there is an inconstant leucocyte subpopulation which behaves differently in response to different lytic agents. In the paragraph bridging the columns of page 252, Dixon teaches that canine leucocytes **did not show significantly increased lysis** when subjected to Zapoglobin at approximately four times the standard concentration, but did do so on exposure to the standard concentration for longer than five minutes. This is compared with results in a paper by Halliday for bovine leukocytes **which did show a concentration dependent effect** to the lysing agent.

An improved electronic method for counting bovine leukocytes by the Coulter method is described by Halliday. The method was developed following the observation that the standard Coulter method generally gave higher results than visual hemocytometer counts. Errors inherent in the standard Coulter method were investigated. The new method is compared with the standard method and with hemocytometer counting. In the standard method the sample is diluted with 20 ml of diluent followed by six drops of the lysing agent to form the solution that after five minutes is counted. The modified method adds the lysing agent to 1 ml of diluent followed by the sample. This is mixed with the remaining 19 ml of diluent after 15 seconds to form the mixture that is counted after five minutes. This is the reference that is discussed in the Dixon reference. The reference shows that this change modifies the count so that it more closely resembled the hemocytometer counts. The last paragraph discusses the possibility that similar leukocyte variations exist for blood from sheep and cats. The first paragraph of the paper teaches the increasing use of electronic counting instruments that were originally developed for human hematology in the hematological examination of animals.

In the paper Robertson discussed modifying staining methods for avian blood cells. In the paragraph bridging pages 881-882 Robertson teaches that prior investigators performing leukocyte counts had developed a diluent for counting avian blood cells due to the inability to destroy the nuclei of the avian red blood cells with the diluent used for removing the non-nucleated mammalian red blood cells.

In the paper O'Daly discusses extract factors that lyse mammalian cells. Cell-free extracts of Trypanosoma cruzi, Leishmania donovani, and Leishmania mexicana, cultivated in medium supplemented with 5% fetal calf serum, contained a factor that induced lysis of mammalian red blood cells and Vero cells. All the lytic activity was in the insoluble fraction of parasite extracts obtained after centrifugation at 100,000 g for 2 hours. The lytic agent was pronase, trypsin, and temperature resistant. The optimum pH of the lytic effect was pH 6.5. Normal red blood cells of several mammalian species had different sensitivities to the agent. The lipid phase of T. cruzi ext. contained the total lytic activity. With respect to this figure 3 shows a concentration dependent effect on the lysis properties. Figure 4 and its discussion on page 226 show a clear variation based upon species for the lysis of red blood cells. The last paragraph of page 229 discusses what these two observations mean in terms of the cells and their hemolysis kinetics. Albumins of different animal species at 1 mg/mL, completely inhibited the lytic activity of the extracts (see figure 7).

In the paper Callan evaluates an automated system for hemoglobin measurement in animals. The system was evaluated for its accuracy in measuring blood Hb concentration in animals by comparing it with standard techniques and for its suitability in veterinary practice. Blood samples, anticoagulated with potassium EDTA, from 78 healthy animals (33 dogs, 17 cats, 13 horses, and 15 cows) and 58 dogs and 4 cats with various blood abnormalities (10 anemia, 11 polycythemia, 21 lipemia, 16 leukocytosis, and 6 icterus) were analyzed. In all species, blood Hb concentration of healthy animals determined by the system was comparable to that measured by standard cyanmetHb methods (ie, an automated counter; rI = 0.987 to 0.998 and a Hb kit, rI = 0.946 to 0.993). In the second full paragraph of page 1763, Callan teaches that due to the variability between species an instrument would need to be calibrated for each species.

In the paper Weiser discusses the modification and evaluation of a multichannel blood cell counting system for blood analysis in veterinary hematology. The Coulter Counter Model S550 blood cell counting system was modified for use in veterinary hematology by increasing both the erythrocyte and leukocyte aperture currents to 225 V and 195 V, respectively, followed by calibration with human blood. It was evaluated by use of 350 samples from dogs, cats, horses,

and cows. Values for leukocyte count, erythrocyte count, mean corpuscular volume, and hematocrit generated by the S550 were compared with values generated by an automated multichannel counter with histogram capability and other reference procedures when appropriate. Mean differences for values between S550 and reference values were less than calibration tolerance limits for the instrument. Correlation coefficients were excellent for all values of each species. To assess behavior of leukocytes of the different species with respect to the counting threshold, leukocyte size distribution histograms were generated for all samples analyzed on the S550. Means for mean leukocyte volumes in diluent and lysing reagents were 55.5, 56.6, 67.4, and 72.8 fl for dogs, cats, horses, and cows, respectively. Canine leukocyte counts, because of small leukocyte size, were an average of 14% less for 5 samples analyzed on the unmodified instrument, compared with analysis after increasing the leukocyte aperture current. Leukocyte threshold failures attributable to interfering particles, resulting in falsely high counts, were recognized in 14%, 10%, 8% and 0% of feline, bovine, canine, and equine samples, respectively. The magnitude of error in these samples averaged 5% for cows and dogs, but was considered not important. However, leukocyte counts of feline samples in this group averaged 44% falsely high. In the last full paragraph of page 411, Weiser teaches that due to the variability between species leukocyte behavior in lysing reagent systems would need to be calibrated for each species.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate software/database for multiple species including differences in lytic agents as taught by Kabata or differences in sensitivity to lytic agents as taught by O'Daly into the Yamamoto device and method and control the device to perform the optimum process for each different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from multiple species and that due to differences in the morphology of the blood cells of the different species as clearly shown by O'Daly, an optimized process including reagent sample compositions would have been required for each species as shown by Callan, Dixon, Halliday, Robertson, Taylor and Weiser. Additionally since O'Daly shows a clear concentration dependent response, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate means

to produce different concentrations of lytic agent based on the species into the device and method of Yamamoto because of the difference in sensitivity to a particular lytic agent as shown by O'Daly.

4. Claims 27-30, 32-35 and 38-45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cellect Hematology in view of Kabata, Taylor, Dixon, Halliday, Robertson or O'Daly and Callan or Weiser (JAVMA 1987). In the figures and associated discussion Cellect Hematology teaches a fully automated blood analyzer and method for making blood particle analyses. In the figure on pages 5 - 6 Cellect Hematology shows the major systems of the instrument including at least one positive displacement syringe pump and stepper motor in fluid communication with a mixing chamber (dilution manifold) and a source diluent. A sample is removed from a sample container by a sample probe and the at least one pump transfers the sample and diluent to the dilution manifold. A lysing reagent is also provided during an analysis. The blood sample is analyzed for particles through a sensing orifice (counting manifold). The device has a controller (microprocessor) for controlling the device and analyzing the result. On page 1 in the first column, Cellect Hematology teaches the ease in adapting the instrument to add on new tests. Cellect Hematology does not teach a multiple species database having different lysing compositions for each species which are mixed for blood samples from the different species.

In the paper Kabata teaches the analysis of the hematologic values of peripheral blood from normal adult rabbits using five different automated flow cytometers. During the analysis the software designed for human blood analysis was used. In the second paragraph of page 613 Kabata teaches that it is known that rabbit blood cells are known to differ from human blood cells in several aspects and suggests adapting the software for animal blood. Pages 614 - 615 discuss how the different automated systems work to obtain the various blood cell populations. It is noted that most of the automated systems incorporate a lysing reagent in the various methods. The rest of the article reports the results and discusses its significance. Of importance to the instant claims is the discussion on page 618 regarding the problems in determining the white blood cell differential counts. The first paragraph also teaches that the leukocytes of rabbits have

several morphologic features that differ from human leukocytes. In the second to last paragraph Kabata teaches that automatic counting of **all** white blood cell sub-populations in animals would require different software. Also taught was the failure of Technicon software designed for use with rat or dog blood to give as reliable of results for rabbit blood as the software designed for humans. Since the Technicon software for rats and dogs give different results, the two sets of software are different.

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The magnitude of error in these samples averaged 5% for cows and dogs, but was considered not important. However, leukocyte counts of feline samples in this group averaged 44% falsely high. In the last full paragraph of page 411, Weiser teaches that due to the variability between species leukocyte behavior in lysing reagent systems would need to be calibrated for each species.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate software/database for multiple species including differences in lytic agents as taught by Kabata or differences in sensitivity to lytic agents as taught by O'Daly into the Cellect Hematology method and device and control the device to perform the optimum process for each different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from multiple species and that due to differences in the morphology of the blood cells of the different species as clearly shown by O'Daly, an optimized process including reagent sample compositions would have been required for each species as shown by Callan, Dixon, Halliday, Robertson, Taylor and Weiser. Addisionally since O'Daly shows a clear concentration dependent response, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate means to produce different concentrations of lytic agent based on the species into the device and method of Cellect Hematology becasue of the difference in sensitivity to a particular lytic agent as shown by O'Daly.

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The O'Daly reference shows a clear species dependent response to a lytic agent and a clear connection between the lytic agent concentration and the amount of lysis which occurs. This clearly supports and enhances the teachings of the Dixon, Halliday and Robertson references which clearly show that there is a species dependent response to the diluent/lyse agent. Halliday shows that by an exposure of bovine blood to a lyse concentration that is about 20 times more concentrated than usual, the leukocyte count becomes closer to the count obtained by the reference hemocytometer count. The Dixon reference clearly shows that there is not the same concentration dependent effect for canine blood as was found by Halliday. Robertson teaches that prior investigators have changed the diluent/lyse used for

counting avian leukocytes because the diluent used to remove (lyse) mammalian red blood cells without a nuclei was not capable of destroying the nuclei in avian red blood cells. Thus these three references collectively show that there are species dependent differences which require a difference in the diluent/lyse used to allow the analysis of the leukocytes to be performed. This would have given an expectation that different species may require a different concentration of a lysing agent for optimal performance. This would have motivated one of skill in the art to determine effective concentration ranges for a lysing agent to be used with more than one animal species. The additional references add further indications or expectations that the blood from different species are different and must be treated differently in a flow analysis as taught by the Cellect Hematology or Yamamoto references.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art relates to measuring properties of animal blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner can normally be reached Monday through Thursday and some Fridays from about 7:30 AM to about 5:00 PM.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Another number for official papers is (703) 305-3599. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist

August 8, 2001

ARLEN SODERQUIST
PRIMARY EXAMINER